OFFICE OF SPECIAL MASTERS

No. 99-271V

Filed: April 19, 2002

SERITA L. SMITH, legal representative of HUNTER JAMES ALEXANDER SMITH,	*	
Petitioner,	*	
v.	*	Published
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Phillip Bartley Ball, Princeton, West Virginia, for petitioner.

Glenn MacLeod, United States Department of Justice, Washington, D.C., for respondent.

ENTITLEMENT DECISION

GOLKIEWICZ, Chief Special Master.

I. PROCEDURAL BACKGROUND

In this matter filed under the National Vaccine Injury Compensation Program, petitioner claims her son, Hunter James Alexander Smith, suffered a Table encephalopathy as a direct result of a Measles-Mumps-Rubella ("MMR") vaccination administered to him on May 1, 1996.[1]

[1]The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (1986) (codified as amended at 42 U.S.C.A. §§300aa-1 through -34 (West 1991 & Supp. 2001)) ("Vaccine Act" or "the Act"). References shall be to the relevant subsection of 42 U.S.C.A. §300aa.

Amended Petition ("Amended Pet.") at 1, 5, filed May 26, 2000.[2] Petitioner alleges Hunter's encephalopathy occurred eight days after the vaccination with the onset of "uncontrollable crying," limp body, eye deviation, and 20 minutes of "rhythmic jerk[ing] of all [his] extremities." Id. at 2. Petitioner believes this severe, post-vaccinal seizure event resulted in her son's subsequent seizure disorder. Id. at 5. Today, "Hunter suffers from a severe seizure disorder with brain damage in both temporal lobes and both hippocampi, the right side being more affected than the left." Id. Respondent disputes that Hunter suffered any compensable Table or off-Table injury. Respondent's Report at 2, 6-13, filed August 2, 1999; Respondent's Supplemental Rule 4 Report at 2, filed August 22, 2000.

The parties presented medical expert testimony during two evidentiary hearings.[3] Dr. Darrell Lewis, Hunter's treating physician, testified for petitioner and Dr. John MacDonald testified on respondent's behalf.[4] While given the opportunity, the parties did not submit post-hearing briefs. The case is now ripe for decision. After considering the totality of the evidence, the court finds petitioner did not demonstrate by a preponderance of the evidence that Hunter's MMR vaccination presumptively or actually caused his injuries.

II. FACTUAL BACKGROUND

Medical records

Hunter was born on April 17, 1995, in Oceanside, California, following an uncomplicated pre-natal course and delivery. P. Ex. A at 1; P. Ex. H at 2, 7. He was a normal newborn with APGAR scores of eight and nine at one and five minutes respectively. P. Ex. H at 7, 20, 80; P. Ex. I at 1-2. Other than suffering conjunctivitis and slight facial and chest jaundice shortly after his birth, he was a healthy newborn. P. Ex. H at 7; P. Ex. I at 2, 3-5. He remained well and developmentally and neurologically normal in the weeks and months following his birth, according to his well-baby visits. P. Ex. J at 1-2, 3-4, 5-6, 7-8. The only concern raised during this time was a possible sebaceous adenoma[5] on his head which was noticed at his two-week appointment. Id. at 2, 7-8. In April 1996, Hunter walked, said "mama" and "dada," towered toys and was otherwise healthy but

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[2]Petitioner claimed initially a Table residual seizure disorder, but the Secretary eliminated this presumptive injury prior to this petition's filing. Petition at 1, filed May 3, 1999; 62 Fed. Reg. 7685, 7688 (Feb. 20, 1997). Petitioner now claims a Table encephalopathy.

[3]The second hearing was necessitated by a recording equipment malfunction during the first hearing.

[4]The December 19, 2000 hearing transcript (filed May 4, 2001) is cited as "Tr. I at #." The September 12, 2001 hearing transcript (filed September 19, 2001) is cited as "Tr. II at #."

[5]A "sebaceous adenoma" is the "nevoid hyperplasia of sebaceous glands, forming multiple yellow papules or nodules of the face." Dorland's Illustrated Medical Dictionary 28 (27th ed. 1988).

for "slow normal speech development" for a one year old. Id. at 9-10. Hunter received the first administration of his MMR on May 1, 1996, shortly after his first birthday. P. Ex. K at 2.

Eight days later, on May 9, 1996, at approximately 8:53 p.m., paramedics responded to Hunter's home for a prolonged seizure.[6] P. Ex. L at 1, 11.[7] Upon their arrival, Hunter had a temperature of 102ºF and was unresponsive and breathing ineffectively. Id. at 1, 2; see also P. Ex. M at 1, 6 (documenting a 103º fever). He was also seizing, had been "seizing for about 10 minutes before their arrival," and "continued to seize, despite being given 6 mg of rectal Valium" by the medics. P. Ex. L at 11; see also P. Ex. L at 1, 3 (documenting that Hunter's seizure began three to five minutes before the medics arrived). Following a second dose of Valium, Hunter seized for 10 more minutes before stopping, bringing his total seizure time to 20 minutes. Id. at 11; see also id. at 3, 18; P. Ex. M at 6, 14 (documenting Hunter's total seizing time as between six and ten minutes). Thereafter, Hunter developed "marked frothy sputum" and became apneic. P. Ex. M at 14; P. Ex. L at 11. The paramedics attempted an IV placement unsuccessfully and then ventilated Hunter with an oxygen mask. P. Ex. L at 1, 11. They transported Hunter to the Tri-City Medical Center Emergency Department, where the treating physician received the following medical history from Hunter's parents:

> [T]he child had had a fever today and had been slightly fussy, but took a nap, woke up from the nap and was playful. He then laid down and had the seizure. The mother found him quite warm at that time. The child has never had a seizure before. He has had no rash. He had no[t] been vomiting. He had slight diarrhea today and has had a trace of a cough, according to the mother. He has had no recent immunizations. There is no family history of seizure activity. The child has had no trauma that they are aware of. He has had no weight loss and has had a good appetite.

Id. at 11. See also id. at 18, 20; P. Ex. M at 6, 14 (documenting Hunter's pre-vaccinal "normal state of good health"). In addition, the parents reported Hunter "has been growing and developing normally" and "[h]e has not been irritable, but was slightly fussy today." P. Ex. L at 11. Hunter's mom thought initially her son's teething caused his fever. P. Ex. M at 29.

During his ER exam, Hunter was "comatose" and "slightly pale" with "frothy respirations,

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[6]The first record noting the seizure's temporal association to the MMR is from the Physician's Notes dated October 25, 1996, written five months after the administration. See P. Ex. O at 10.

[7]The court's copy of petitioner's Exhibit H contains two "sets" of records, with twenty-three pages having duplicate numbering. The court believes twenty-three pages numbered 10-33, which describe care surrounding Hunter's May 1996 seizure, are more accurately continuations of the records from petitioner's Exhibit L and the court cites them as such. The remaining pages in petitioner's Exhibit H, numbered 1-86, cover the prenatal and birthing events.

with some stridorous sounds heard." P. Ex. L at 12. He also had a slightly red left ear and his chest exam revealed "[r]honchi bilaterally, with some marked upper airway sounds." Id. Hunter had no rash, petechiae, or purpura. Id. Emergency room personnel performed a spinal tap, and "[a]t this point, the child began to have apneic spells." Id. Hunter was then ventilated and intubated. Id. at 12, 19; P. Ex. M at 14. Medical personnel conducted several tests to determine the cause of Hunter's condition. A stool culture was negative for salmonella, shigella, and campylobacter; in addition, no e. coli 1057:H7 was isolated. P. Ex. L at 28. A radiologist interpreted his CT scan as negative. Id. at 16, 29. Laboratory results showed a "[w]hite count [of] 8000, hemoglobin 11.5, hematocrit 34.2, with differential showing 39 segs, 3 bands, 53 lymphs, and 5 monocytes." Id. at 12. The treating physician deemed this a "viral shift" and considered viral pneumonia in the differential diagnosis. Id. at 12-13. He stated: "His spinal fluid is clear. I find no evidence of meningitis and I feel that if this is pneumonia, it is viral." Id. at 12, 13. The treating physician also diagnosed Hunter with a prolonged febrile seizure and a mild left otitis media; he believed Hunter's "slightly red left ear" "could be another source of his fever." Id. at 13.

Within about an hour after this seizure episode, at 10:00 p.m., Hunter was awake and demonstrated "good eye contact." P. Ex. L at 22. The hospital transferred him shortly after midnight to the Pediatric Intensive Care Unit at Balboa Naval Hospital. Id. at 6; P. Ex. M at 24. At this time, he was awake, ventilated, in stable condition with a rectal temperature of 98º. P. Ex. L at 6, 7. Upon his arrival at the Naval Medical Center, he remained slightly alert, afebrile, and in stable condition with normal tone (a review of his tympanic membranes was deferred at that time). P. Ex. M at 5, 6. Once in the PICU, he began to self-extubate; the treating physician assessed him as having probable febrile seizure and apnea secondary to his valium overdose and "prob[able] viral syndrome although need to eval[uate] for OM [otitis media]." Id. at 5, 6, 14. Another treating physician made the following evaluation: "Of note, Tri-City's exam revealed a [left otitis media]. I was less impressed by this upon my exam early this morning, there was a small rim of erythema, but no effusion & no [decreased] mobility of the [tympanic membrane]." Id. at 14; but see id. at 15 (different treating physician offering an impression that Hunter had a "Febrile illness: OM [otitis media] vs. viral syndrome."). Hunter had a negative family history for seizures and no childhood illnesses (other than ear infections), sensitivities or allergic reactions. Id. at 7.

By 6:29 a.m. on May 10, 1996, Hunter was still slightly groggy, "but more awake and alert." Id. at 12. His bilateral breath sounds were essentially clear with "reffered upper airway congestion noted." P. Ex. M at 12. He was also afebrile. Id. A neurological exam conducted three hours later noted Hunter was "drowsy from valium given earlier, but alert." Id. He was "[r]ecognizing [his] parents." Id. By 1:00 p.m., Hunter was afebrile, "awake and alert" and "smiling/laughing with [his] parents." Id. at 9. At 7:00 p.m., his "mom states [patient] still is not himself, cont[inues] to be sleepy/lethargic." Id. at 10. By 9:53 p.m., just 25 hours after the onset of his seizure, Hunter was sleeping comfortably with a 100.3º temperature.[8] P. Ex. M at 10. By 1:00 a.m. on May 11, 1996,

[8]Another exam conducted sometime on May 10, 1996, at the Naval Hospital describes Hunter as "[without] rash" and "somnolent but arousable, [with] good tone [and] color." P. Ex. M at 13. His right and left external auditory canals were within normal limits as was his right tympanic

Hunter's fever spiked to 103.8 rectally and he had "passed [a] large, loose, dark green stool"; medical personnel treated him with Tylenol. Id. Over the course of the early morning, Hunter slept at long intervals and remained tired, but appeared alert when awake; he also was not eating well. Id. at 28. He remained feverish (103.8º) until 9:45 a.m. and was "[s]leepy but arousable." Id. at 20. He also continued to have "[g]reen loose stools" and "minimal erythema around [his left] [tympanic membrane]." Id. His febrile seizure and valium induced apnea was considered "all secondary" to his left otitis media or gastroenteritis. Id. The course of treatment included continued medication with Amoxil for his previously diagnosed otitis media. P. Ex. M at 20. The pediatric staff attributed the gastroenteritis to "[p]robably Rota or other viral source"; they planned to rule out shigella. Id. His stool culture, urinalysis, and CSF culture returned negative. Id. at 45. By the morning of May 12, 1996, Hunter was "cheerful," "awake and playing in [his] mother's arms," and "having breakfast and tolerating this well." Id. at 47. The hospital discharged Hunter that day, in good condition, with a final diagnosis of febrile seizure, post-valium overdose, and a left ear infection. Id. at 39, 44, 45. He was sent home with only a prescription for Amoxil to treat his ear infection. Id. at 39, 44. On follow-up eight days later, his left tympanic membrane had "fluid" and "minimal erythema," but the infection was resolving and he was to continue on his prescription. Id. at 41.

Three months later, at his fifteenth-month well-baby visit (August 5, 1996), the pediatrician recorded no complaints, prior history, or allergies. P. Ex. J at 12. About two weeks later on August 21, 1996, thirteen days after the administrations of the chicken pox and DPT vaccines, Hunter suffered his second seizure. P. Ex. O at 10. Hunter's mother became aware of his seizing when "she was awakened by [his] making a snorting-type noise." P. Ex. N at 14. Hunter's convulsion involved both his upper and lower extremities and began five minutes prior to and continued upon the medics' arrival. Id. at 1, 3, 13, 14. He was lethargic and not responding to verbal stimuli and treated with Valium. Id. at 1, 3. His mother reported a negative history for an increased temperature but noted Hunter's off and on episodes of vomiting the day before. Id. at 3.

When the medics arrived with Hunter at Tri-City, Hunter suffered another generalized seizure in the ER. Id. at 3, 14, 15, 17. His temperature upon admission was 98.4º rectally and the history states he "vomited six times today." Id. at 13, 14. Overall, Hunter "was initially not febrile and had a seizure lasting approximately 45 minutes," but during the course of his ER stay, his "fever increased to 102º." P. Ex. N at 16; see also P. Ex. O at 10. Hunter was treated with IV fluids, Ativan, Rocephin ("because of the possibility of a central nervous system infection"), Tylenol, and Pediaprofen. P. Ex. N at 7, 16. The history also states he "recovered uneventfully" from his May febrile seizure and that he "ha[d] a recent history of febrile-type illness, which was evaluated at Camp Pendleton. [He] was treated with two days of Septra for a 'possible bacterial infection.'" Id. at 14. Hunter's neurologic exam after this second seizure was normal. Id. at 15. His chest x-ray also appeared normal and "the only source of infection appear[ed] to be the urine, which reveal[ed] pyuria and bacteriuria." Id. at 15, 16. By 7:00 a.m., Hunter was irritable and "lethargic," but awake, "more responsive," and consolable by his parents. Id. at 18. He was diagnosed with a prolonged

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membrane but his left tympanic membrane showed a "small ring of erythema" which was otherwise within normal limits. Id.

seizure and a urinary tract infection and transferred in stable condition with a 101.3º temperature to the Balboa Naval Hospital for continuing care. Id. at 7, 16. A CT conducted on August 22, 1996, during his treatment for this second seizure was normal as was an EEG. Id. at 25; P. Ex. O at 4, 10.

A little more than a week later, Hunter was seen by Dr. Peggy Shaffer on October 3, 1996, at Camp Pendleton Naval Hospital for a complaint of 1-2 minute episodes of unresponsiveness not associated with decreased tone. P. Ex. S at 2. In these episodes, Hunter's "face turn[ed] red or pale," and he became "clammy," with "repeated swallowing & emesis followed by 2-3 [hours] of sleep." Id. On exam he was very active and ambulatory and his neurology exam, while difficult to assess because of his agitation, was symmetrical and nonfocal; Dr. Shaffer diagnosed Hunter with a seizure, and with differential diagnoses including migraine and behavior. Id. On October 25, 1996, at 18 months of age, Hunter was admitted to Camp Pendleton's Naval Hospital for a three day history of similar, brief staring and swallowing episodes. P. Ex. O at 4, 8, 10. He was alert, afebrile, and interacting with his parents upon admission. Id. at 4, 11, 12. His parents denied a recent history of illnesses and reported that Hunter "[h]as 'spells' where [he] swallows a lot, stares & goes asleep for hours afterwards." Id. at 4; but see id. at 8 (documenting "reports [of] cold/rhinorrhea in past few days" without nausea, vomiting or diarrhea.). Over the course of his five day hospitalization, Hunter's neurological and developmental exams were normal; his treaters repeatedly described him as calm, consolable, alert, active, and playful. Id. at 11, 12, 20, 57-58, 64-65, 66, 72-74. He was discharged on October 29, 1996, on valproic acid (Depakene). Id. at 20.[9]

Hunter remained seizure free until November 4, 1996, when he was again admitted to the Camp Pendleton Naval Hospital for treatment of "multiple cyanotic spells" or "shallow breathing" associated with paleness. P. Ex. P at 5, 7. His parents denied "any fevers or jerking [movements]." Id. at 7. An MRI conducted at this time returned within normal limits. Id. at 5. Hunter suffered no loss of skills and his development was on target although he did have a history following his October 1996 seizures of "some behavioral [reactions]" to his valproic acid prescription which prompted his physicians to lower the dose for a while before slowly increasing it. P. Ex. S at 21, 23. By November 6, 1996, he was steady in his gait, alert, active, and free of seizures and cyanotic spells; he was thereafter discharged with a diagnosed mixed seizure disorder of unknown etiology. Id. at 24; P. Ex. P at 28, 30.

Thereafter, Hunter suffered multiple instances of seizure activity, which at times increased in frequency and changed in pattern. See, e.g., P. Ex. S at 28, 42, 44; P. Ex. R at 5, 10, 14. He also experienced behavioral changes. For instance, on December 3, 1996, Hunter's mom telephoned Dr. Shaffer's office complaining that Hunter was "having tantrums and head banging this afternoon similar to those he had when he first started VPA." P. Ex. S at 35. Two hours later after receiving Tylenol he was sleeping and feeling better and he returned to normal by the next morning. Id. On

[9]During his stay, Hunter had a dermatology consultation about the sebaceous adenoma on his right forehead. The dermatologist determined that the nevus sebaceous indicated "[n]o signs of tuberous sclerosis, but skin signs . . . may not appear till age 5. Tubers may be first sign, so the MRI scheduled may be diagnostic." P. Ex. O at 75.

January 14th, following treatment for more staring/swallowing/cyanotic seizures, Hunter's growth and development were considered appropriate for his age and he was diagnosed with a partial complex seizure disorder. P. Ex. R at 5, 13, 14.

On February 4, 1997, Hunter was seen by Dr. Darrell V. Lewis, Jr. of the Duke University Medical Center for a second opinion. Dr. Lewis wrote that following changes in the anti-convulsant dosages, Hunter suffers "some side effects consisting of head-banging, irritability and clumsiness after each dose, which will last for a few days until he gets used to the increased dosage." P. Ex. T at 4. He noted Hunter's head growth "has been growing along the 80th percentile, very smoothly since birth." Id. Dr. Lewis felt the November 1996 MRI scan "was normal and it was a good study. It showed normal hippocampi bilaterally and no cortical dysplasia."[10] Id. Dr. Lewis further concluded based on Mrs. Smith's interview and a "Denver developmental screen . . . that [Hunter's] development was on target." Id. When asked by Hunter's parents the possible role of the immunizations in their son's seizures (since Hunter had two seizures temporally to the MMR and the DPT/varicella vaccines), Dr. Lewis noted that Hunter's October 1996 seizures occurred absent any preceding vaccinations and **"it is not possible to determine whether the immunizations had any role in his seizures, since he did not suffer a characteristic encephalitis following the immunizations, which would be the only clear evidence of an immunization-related encephalopathy."** Id. at 5 (emphasis added). Dr. Lewis raised the possibility that Hunter's seizures were related to his sebaceous nevus "which can occur in about 10% of children who have these lesions," although Dr. Lewis cautioned that "[t]his is a possibility which we will not be able to either prove or disprove, but it is worthwhile keeping in mind." Id. He also noted Hunter's previous, normal amino acid, organic acid, toxic and electrolyte screenings. Id. at 4.

Hunter continued to suffer seizures despite his various anti-convulsant medications. See, e.g, P. Ex. U at 1-3. Hunter also showed signs of speech delay. A year after his first seizure, on May 22, 1997, Hunter was "only saying a few words . . . [and] tend[ed] to point at things and grunt." Id. at 3. This was similarly observed by Dr. Lewis in his June 3, 1997 visit with Hunter: "[Hunter's] development is a little bit slow. He has 10 words and does not use them in combination. He does pretend to do housework and he does point to pictures and point to his body parts. He is no[t] scribbling yet but he can stack 6-7 blocks. His gross motor skills seem normal." P. Ex. T at 9. An MRI conducted during the visit "was interpreted on a preliminary report as showing mild atrophy diffusely and atrophy of both hippocampi with right more affected than the left and some increase in signal in the right hippocampus" which Dr. Lewis considered "compatible with [his] idea that [Hunter] has partial complex seizures of temporal lobe origin [although he is] puzzled because the hippocampal injury appears to be on this preliminary reading bilateral and they also mention some

[10]In a follow-up letter on March 14, 1997, Dr. Lewis stated that from his second review of the MRI, "it is difficult to completely visualize the parts of the brain called hippocampus" and "[Hunter's] seizures . . . may be arising from this structure in the temporal lobe of the brain called the hippocampus, and, therefore, it would be important at some point in time, if his seizure[s] continue, to get an MRI scan to visualize that area of the brain well." P. Ex. T at 6.

atrophy."[11] Dr. Lewis opined in a June 25, 1997 letter to Hunter's parents that the "brain damage [noted on the MRI] is causing [Hunter's] seizures, which are partial complex in type." Id. at 13.

Dr. Hopper (Dr. Hamaker's colleague) reported on Hunter's behavioral problems following his July 11, 1997 appointment: "family states child not sleeping, kicking, head banging, throws things, screams. Every time family increases tegretol symptoms worsen."[12] P. Ex. U at 4. This complaint resulted in the adjustment of Hunter's seizure medication. Id. Dr. Lewis's September 2, 1997 examination letter states Hunter "[a]t 28 months . . . is saying a few words such as 'pee pee now' or 'go bye bye' and 'mama and dada.' He can point to several body part but he cannot identify pictures in books. He is entering speech therapy and is soon to have his hearing evaluated." P. Ex. T at 16. He confirmed the diagnosis is "probably partial complex partial seizures of temporal lobe origin."[13] Id. at 17. Hunter's speech delay continued through the end of 1997, although his motor milestones, coordination, visual tracking, and walking all remained fine or appropriate for his age. P. Ex. U at 34, 36-37. Today, in addition to having complex partial seizures, Hunter suffers from behavioral and learning problems. Tr. I at 4. No contemporaneous records causally associate the onset of Hunter's seizures with his MMR vaccine.

Affidavits

Hunter's parents submitted affidavits with the initial petition. In addition to some of the facts detailed above, they aver Hunter was medically well in the eight days following his vaccination until the onset of his seizure on May 9, 1996, and that his first seizure began following a terrible scream and an inconsolable crying spell. P. Exs. C and D at 1. They also allege Hunter "did not appear to have a high temperature" at the time of his seizure, but neither took his temperature. Id. Following his transfer to Balboa Naval Hospital after his first seizure, Mr. and Mrs. Smith further state that Hunter "continued to have a series of seizures, one of which consisted of his arm drawing up, and

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[11]The official report from the June 3, 1997 MRI reads: "moderate diffuse volume loss" and "significant hippocampal volume loss bilaterally, much greater on the right as compared to the left. There is also increased signal within the right hippocampus on several images, suggesting the possibility of mesial temporal sclerosis in a patient with seizures." P. Ex. T at 11. Dr. Stan S. Hamaker concurred that the results of this MRI were "consistent with Dr. Lewis'[s] diagnosis of partial complex seizures of temporal lobe origin on the right." P. Ex. U at 22.

[12]Dr. Hamaker, Hunter's primary treating physician at the time of the petition's filing, opined in his affidavit that Hunter has partial complex seizures which, with a "high probability," "resulted from the MMR vaccination given on May 1, 1996." P. Ex. E at 2. He bases this opinion on the onset of the seizures eight days after the vaccination and the fact that "no other infection, toxin, trauma, or metabolic disturbance . . . was identified in the medical records, or upon [his] examination of Hunter." Id. Dr. Hamaker did not testify at either of the evidentiary hearings.

[13]An EEG conducted on September 2, 1997, was normal; the report noted "[p]atients with a known seizure disorder may have normal interictal EEG's." P. Ex. T at 15.

mouth drooping as if Hunter had a stroke. This seizure lasted for over 24 hours before it subsided." Id. at 2. Finally, the Smiths assert Hunter "experienced at least twenty seizures within six (6) months of his MMR vaccination." Id.

III. MEDICAL EXPERT REPORTS AND TESTIMONY

Dr. Darrell V. Lewis, Jr.

Dr. Lewis, Hunter's pediatric neurologist, provided an affidavit in this matter and testified on petitioner's behalf.[14] [15] Dr. Lewis opines that Hunter suffered a Table encephalopathy, as defined by the Act,[16] and that his partial complex seizure disorder possibly "resulted from a severe febrile

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[14]The court's copy of petitioner's Amended Petition has Dr. Lewis's CV attached as Exhibit A and his affidavit (expert report) attached as Exhibit B, but the content of petitioner's Amended Petition cites the reverse. To be consistent, the court references Dr. Lewis's report as Exhibit A and his CV as Exhibit B.

[15]Dr. Lewis has been Hunter's treating pediatric neurologist since February 1997. Tr. I at 4. He is certified by the American Board of Psychiatry and Neurology with a special competence in Child Neurology. Amended Pet.'s Ex. B at 1. He possesses added qualifications in clinical neurophysiology and electroencephalography. Id. Dr. Lewis holds a medical degree from the University of Minnesota and completed post-graduate training in pediatrics and neurology at various medical institutions. Id. at 2. He has held several teaching positions in pediatric neurology and neurobiology. Id. at 2-3. He currently serves as the Acting Chief of the Division of Pediatric Neurology at Duke University Medical Center and as a professor in the Departments of Pediatrics (neurology) and Neurobiology at the Medical Center. Id. at 3. Dr. Lewis belongs to a number of professional organizations, including the American Epilepsy Society, Pediatric Neurology Society, Society for Neuroscience, and the International Brain Research Organization. Id. at 11-12. He has published in peer-reviewed journals and written chapters and reviews on topics involving the brain and seizures. Id. at 3-11. Dr. Lewis appeared sincere in his belief that the vaccine caused Hunter's initial seizure and subsequent permanent injuries and he admitted honestly when scientific limits on hippocampal injuries or other matters prevented him from testifying conclusively.

[16]Dr. Lewis does not explain Hunter's injuries in terms of the Table definition, but he believes his patient's encephalopathy "would be an incito-toxic injury" to the hippocampus. Tr. I at 16-17. He accepts Hunter did not suffer status epilepticus on May 9, 1996, but is unsure whether the seizure caused the encephalopathy or vice versa. Id. at 11, 35. He holds firmly to his earlier opinion in the medical records that Hunter's seizures are not vaccine-related because the child suffered no characteristic "encephalitis" which is an inflammation or infection of the brain. Id. at 39, 50-51; P. Ex. T at 5. Dr. Lewis differentiates "encephalitis" from an "encephalopathy," defined by him as "brain dysfunction." Tr. I at 51.

seizure triggered by the MMR vaccination given on May 1, 1996."[17] Amended Pet.'s Ex. A at 1, 2; Tr. I at 10-11. Specifically, Dr. Lewis theorizes it is "possible," but not provable, that the vaccine caused Hunter's fever, the fever produced a prolonged convulsion, the convulsion permanently injured an important part of Hunter's brain, the hippocampus, and this "hippocampal sclerosis" manifested later in Hunter as intractable epilepsy and behavioral and learning problems.[18] Tr. I at 12-13, 15, 16-17, 18, 34, 41.

Dr. Lewis's theory is rooted in the following. First, he believes it more probable than not that the vaccine caused the fever "[b]ecause, there was no real proof of a viral infection, and because [Hunter] had two immunizations, and he had been fussy." Tr. I at 19, 30. The fever was also high enough to cause a seizure. Id. at 18. Second, Dr. Lewis states that 10% of those experiencing complicated febrile seizures will suffer a hippocampal injury immediately following the seizures where the hippocampi becomes "larger than normal, with abnormal signal." Id. at 36. Thus, once Hunter experienced a convulsion, he had a 51% chance it "would result in hippocampal sclerosis."[19] Id. at 16. Further, Hunter's abnormal MRI from June 1997 documents a bilateral hippocampi injury.[20] Id. at 4. Dr. Lewis states: "These findings indicate that Hunter is suffering partial complex seizures of [the] temporal lobe origin . . . [and that] [t]his brain damage is causing [the] seizures." Amended Pet.'s Ex. A at 1. Third, Dr. Lewis notes Hunter now suffers from the possible sequela of a hippocampal injury – behavioral and learning problems. Tr. I at 4, 34, 36. Dr. Lewis explains, "[t]here's no clinical sign, unfortunately, of a hippocampal injury, except the later development of

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[17]He bases this opinion on his "examinations of Hunter, review of all medical records in [his] possession of Hunter, [and] especially in light of the onset of seizures occurring within several days of receiving the first MMR vaccination." Amended Pet.'s Ex. A at 1. He also bases his opinion on the absence of another cause, including infection, toxin, trauma or metabolic disturbance. Id.

[18]Dr. Lewis testified the febrile seizure would have occurred "either because he has a genetic predisposition, or some other problem with his brain at the time." Tr. I at 12. Dr. Lewis admits science is at odds over what comes first, the seizures or the hippocampal injury; his work shows seizures can cause the hippocampal injury but the reverse can occur as well. Id. at 15-16.

[19]The court is not clear on how Dr. Lewis arrived at his opinion that Hunter had a 51% chance of suffering hippocampal sclerosis based on the notion that 10% of those suffering complicated febrile seizures will suffer the injury.

[20]Dr. Lewis readily admits his testimony conflicts with his earlier written statements. Tr. I at 38. During the hearing, he stated that the hippocampi was not visible on the first MRI which contradicts his medical opinion in the records that the November 1996 scan was of sufficient quality. Id. at 6-7; cf. P. Ex. T at 4. He suggested a scan with special imaging views would show whether Hunter suffered a bilateral hippocampi injury. Tr. I at 6-7. Of course, this was done in June 1997. Dr. Lewis also opines that while CT scans are not done to review the hippocampus and he did not review Hunter's, the hippocampal injury would show up there as well. Id. at 7-8.

seizures and learning difficulties."[21] Id. at 34. Dr. Lewis's findings in February 1997, that Hunter suffered no developmental delay even at nine months following his first seizure, do not undermine his opinion of vaccine-relatedness. He freely admits science has yet to determine what problems one should expect following a bilateral hippocampi injury. Id. at 45-46. He notes that in his treatment of one bilateral patient who had the injury before developing seizures, the child is neither developmentally delayed nor mentally retarded, and he would pass the rigorous Denver Developmental screening. Id. at 45.

By attributing Hunter's hippocampal injury to the vaccine and his initial seizure, Dr. Lewis dismisses two alternative causes. The first is Hunter's sebaceous adenoma. Dr. Lewis agrees that while it is possible Hunter's sebaceous adenoma caused his seizure disorder, since it can produce seizures, it is less likely here because 10% of those with the lesion also have MRI results showing cortical dysgenesis, which Hunter's did not. Id. at 40, 49-50. In any event, Dr. Lewis is not aware of "sebaceous nevi producing hippocampal injury." Id. at 50. Dr. Lewis dismisses secondly a viral infection. Tr. I at 29-30. He takes issue with the treating physicians' findings that Hunter had left otitis media at the time of his initial febrile seizure. Id. at 22-25. He disagrees that a slightly red left ear, as described in the records, is necessarily consistent with otitis media; he notes a child can develop red eardrums just from crying or external irritation. Id. at 22, 23, 33. Instead, Dr. Lewis requires a bulging tympanic membrane (eardrum) with fluid behind it before diagnosing an ear infection. Id. at 22, 23-24, 33. In this case, notations that Hunter's tympanic membrane had a "small ring of erythema [but was] otherwise normal" do not lead him to conclude firmly that the child suffered otitis media during his initial seizure. Id. at 23-24, 33. Dr. Lewis also remains unconvinced that evidence in the record of Hunter's diarrhea, high fever, cough, fussiness, and elevated white blood count/viral shift surrounding his first seizure steadfastly establishes a viral infection although these symptoms "could be" evidence of such. Id. at 21-22, 27-28. He notes seizures alone can cause an elevated white blood count or shift. Id. at 30.

Dr. John T. MacDonald

Dr. MacDonald provided an expert report and testified on respondent's behalf in this matter.[22]

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[21]Dr. Lewis opines the hippocampal injury's likelihood may be influenced by the duration of the seizure or one's body temperature. Tr. I at 36. He presumes that during the seizure "there is a release of glutamate excitatory neuro transmitter, that overdrives the neurons of the hippocampus and causes some neuronal death" which initially "manifest[s] itself as swelling, and later on in shrinkage of the hippocampus." Id. After the shrinkage, some individuals will develop temporal lobal epilepsy; with bilateral shrinkage, one may have learning problems. Id.

[22]Dr. MacDonald is a board-certified pediatric neurologist with the Minneapolis Clinic of Neurology and Minneapolis Children's Medical Center. Tr. I at 51-52; R. Ex. D at 1. He is also certified in Psychiatry. R. Ex. D at 1. Dr. Lewis holds a medical degree from the University of Michigan and completed post-graduate training in pediatrics and child neurology at the University's Children's Hospital and the University of Miami Medical Center. Id. He currently teaches pediatric

He opines Hunter's acute symptoms do not satisfy the Act's Table encephalopathy definition. Tr. I at 56, 58; R. Ex. B at 2. Dr. MacDonald reasons that within hours of Hunter's initial seizure, despite being medicated and having overdosed earlier on a drug, the child was active enough to extubate himself. Tr. I at 57; R. Ex. B at 2. Moreover, "[w]ithin 14 hours, he [was] playful, alert, looking around." Tr. I at 58; see also R. Ex. B at 1-2. In addition, "[t]here's no other evidence [in the record] . . . of a child who is comatose or semi-comatose. There's no signs of increased central cranial pressure, no signs that [Hunter] can't inter-relate to his parents or those around him. He makes a very quicky recovery [despite] all the Valium he received." Tr. I at 58; see also R. Ex. B at 2. With "secondary infection of the brain, [one] expect[s] a much more severe alteration of behavior, consciousness" than occurred here. Tr. II at 8-9.

Dr. MacDonald believes for additional reasons that Hunter's acute symptoms are inconsistent with an MMR reaction. For instance, while the vaccine can cause a fever, Hunter's occurred "too far out from the vaccination" to ascribe causation. Tr. I at 54. A MMR-related fever occurs "sooner" and is "more variable and shorter." Tr. II at 10. In addition, Hunter did not suffer those preceding problems which typically occur with a post-vaccinal febrile illness, such as irritability, crabbiness, lack of appetite, changes in the skin (for example, a rash), and acute changes in behavior. Tr. I at 54; Tr. II at 8, 9. Moreover, in Dr. MacDonald's view, the MMR cannot cause the symptoms Hunter *did* experience: diarrhea, cough, otitis media, elevated white blood count, and chest congestion. Tr. I at 55.

Dr. MacDonald is also strongly persuaded by the lack of "other findings of encephalopathy" which one would expect "over a long period of time if the immunization itself is causing a measles-like syndrome." Tr. II at 8. Hunter was still developmentally normal by February 1997 (nine months after the first seizure), according to Dr. Lewis's own findings. Id. at 9-10. Moreover, Hunter's normal November 1996 MRI represented "almost irrefutable evidence that there was not an ongoing brain injury that preceded" the radiological exam.[23] Id. at 5. While Dr. MacDonald agrees Hunter

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neurology at the Minneapolis Children's Medical Center, maintains a private neurology practice, and serves as Editor-in-Chief for Pediatric Journal. Id. at 1-2. Dr. MacDonald also belongs to a number of professional organizations, including the American Academy of Neurology, Child Neurology Society, and Tourette's Society Association. Id. at 2. He has received several research grants, published articles in scientific journals, and written chapters and abstracts on topics involving the brain and seizures. Id. at 3-4. He has further given presentations and lectures on childhood diseases and illnesses, including seizures, and childhood developmental, behavioral, and learning problems. Id. at 5-8. The court is familiar with Dr. MacDonald's previous appearances in vaccine cases; he has consulted for respondent since 1992. Id. at 2. Dr. MacDonald demonstrated significant knowledge about his medical field and its application to the facts of this case. He presented cogent, credible testimony.

[23]Dr. MacDonald reviewed the original CT and the 1996 and 1997 MRIs. Unlike Dr. Lewis, he believes the November 1996 MRI was "an excellent scan" and provided a view of the hippocampus. Tr. II at 5, 6, 22; see also R. Ex. C at 1. He also believes that while "[t]hey did do

suffers from a hippocampal injury, he views it impossible that the child suffered some form of brain damage between May and November 1996, even subtle brain damage from multiple seizures occurring over that course of time, which would have been revealed in the June 1997 scan, but not the November 1996 MRI.[24] Id. at 4-6, 20, 22-23; R. Ex. B at 2; R. Ex. C at 1. For Dr. MacDonald, the abnormal 1997 MRI shows "something that occurred or was occurring probably within weeks or months before that."[25] Tr. II at 24; see also R. Ex. B at 2. Simply put, without an abnormal MRI in November 1996 and post-vaccinal "signs of progressive neurological problems, developmental delays," Dr. MacDonald "cannot logically, medically, or . . . as far as the table, impugn the episode in May of '96 as having any relationship to the damage that's present in '97." Tr. II at 25; see also Tr. II at 9-10, 26. In his opinion, the clinical, radiological, and developmental evidence supports that Hunter's initial seizure was simply a febrile convulsion "which most people would say are benign and have no permanent problems." Id. at 26; see also id. at 14.

Finally, Dr. MacDonald rejects vaccine-relatedness in this case because he believes more probably than not that Hunter's fever and seizure on May 9-10, 1996, were caused by an inter-current viral illness, as evidenced by the treating physicians' diagnosis and treatment for a viral illness (otitis media) and Hunter's demonstration of "standard physical signs of a viral illness."[26] Tr. I at 52-53, 54; Tr. II at 10, 11. These signs included an acute fever, unwell feeling, febrile seizure, lung congestion (bronchi bilaterally and marked upper airway obstruction),[27] unilateral redness of the

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a few extra special cuts in '97, . . . the abnormality, which is so obvious in '97, should have been present on that '96 film." Tr. II at 6; see also Tr. II at 5, 22. He notes that in practice physicians reasonably wait two to three months before conducting the scan "to give the brain time to have that structural change." Id. at 7. Thus, by November 1996, Hunter's brain damage should have been apparent on the initial MRI had it existed Id. He does concede the CT scan was completed so soon after the seizure and is less sensitive than the MRI scans, that it could have missed any ongoing damage. Id. at 6, 7, 21.

[24]Dr. MacDonald also believes no one can determine whether the seizures prior to the 1997 MRI "are signs of an ongoing damage or just an epiphenomenon . . . occurring in the midst of whatever is wrong with [Hunter's] brain." Tr. II at 24; see also Tr. II at 25.

[25]Dr. MacDonald writes in his report: "The cause of hippocampal sclerosis has always been controversial but is thought to be an acquired lesion in most although a pre-existing brain malformation may be present in some cases." R. Ex. B at 2.

[26]Dr. MacDonald notes viral illnesses are the most common cause of febrile seizures. Tr. I at 54; Tr. II at 11. In his opinion, Hunter's 48-hour fever lasted too long were it related solely to the post-vaccinal seizure. Tr. II at 16-17.

[27]Unlike Dr. Lewis, Dr. MacDonald comfortably ascribes these findings in Hunter's chart to viral-caused chest congestion which can accompany ear infections. Tr. II at 12-13. He dismisses that Hunter's Valium overdose or intubation procedure produced these clinical symptoms. Id. at 18.

eardrum,[28] fussiness, and an elevated white blood cell count.[29] Tr. I at 53, 55-56.

IV. THE VACCINE ACT AND RELEVANT JURISPRUDENCE

Causation in Vaccine Act cases can be established in one of two ways: either through the statutorily prescribed presumption of causation or by proving causation-in-fact. Petitioners must prove one or the other in order to recover under the Act. According to §13(a)(1)(A), claimants must prove their case by a preponderance of the evidence. This requires that the trier of fact "believe that the existence of a fact is more probable than its nonexistence before [the special master] may find in favor of the party who has the burden to persuade the [special master] of the fact's existence." Hodges v. Secretary of HHS, 9 F.3d 958, 963 (Fed. Cir. 1993) (Newman, J., dissenting) (citing Concrete Pipe and Products of California, Inc. v. Construction Laborers Pension Trust for Southern California, 508 U.S. 602 (1993), quoting In re Winship, 397 U.S. 358, 371-72 (1970) (Harlan, J., concurring)).

For presumptive causation claims, the Vaccine Injury Table lists certain injuries and conditions which, if found to occur within a prescribed time period, create a rebuttable presumption that the vaccine caused the injury or condition. Once a Table injury has been established by a preponderance of the evidence, the presumption of vaccine-relatedness may be overcome by an affirmative showing that the injury was caused by a factor unrelated to the administration of the vaccine. §13(a)(1)(B). In this case, an encephalopathy is presumptively related to the MMR vaccine if it complies with the definition at 42 C.F.R. §100.3(b)(2)[30] and first manifests no sooner than five days and no later than fifteen days following the vaccination. §100.3(a).

To demonstrate entitlement to compensation in an off-Table case, a petitioner must affirmatively demonstrate by a preponderance of the evidence that the vaccination in question more likely than not caused the injury alleged. See, e.g., Bunting v. Secretary of HHS, 931 F.2d 867, 872 (Fed. Cir. 1991); Hines v. Secretary of HHS, 940 F.2d 1518, 1525 (Fed. Cir. 1991); Grant v. Secretary of HHS, 956 F.2d 1144, 1146, 1148 (Fed. Cir. 1992). See also §§11(c)(1)(C)(ii)(I) and

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[28]Dr. MacDonald states crying causes a bilateral, not unilateral, redness of the eardrums. Tr. I at 53; Tr. II at 19. He rejects that a red eardrum can result from a seizure. Tr. II at 19.

[29]Dr. MacDonald agrees with Dr. Lewis that an elevated white blood cell count may "rule out more serious bacterial infection[s]" but is not dispositive for diagnosis purposes; in this case, the results were "just one more piece of evidence that this child had a viral illness, and it was used by the treating doctors who were treating him for this illness." Tr. I at 55. He also believes it speculative that seizures can cause a shift in the blood count. Tr. II at 12. In his experience, a white count shift "99.9 percent of the time . . . signifies an underlying viral illness" and "in this case, particularly with the fever, an infectious illness would be the most obvious cause" of the shift. Id. But he also concedes that "in routine viral illnesses, . . . we don't expect spinal fluid changes." Id. at 18.

[30]Future references shall be to the section and subsections only.

(II). To meet this preponderance of the evidence standard, "[a petitioner must] show a medical theory causally connecting the vaccination and the injury." Grant, 956 F.2d at 1148 (citations omitted); Shyface v. Secretary of HHS, 165 F.3d 1344, 1353 (Fed. Cir. 1999). A persuasive medical theory is shown by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Hines, 940 F.2d at 1525; Grant, 956 F.2d at 1148; Jay v. Secretary of HHS, 998 F.2d 979, 984 (Fed. Cir. 1993); Hodges, 9 F.3d at 961; Knudsen v. Secretary of HHS, 35 F.3d 543, 548 (Fed. Cir. 1994). Furthermore, the logical sequence of cause and effect must be supported by "[a] reputable medical or scientific explanation" which is "evidence in the form of scientific studies or expert medical testimony." Grant, 956 F.2d at 1148; Jay, 998 F.2d at 984; Hodges, 9 F.3d at 960.[31] See also H.R. Rep. No. 99-908, Pt. 1, at 15 (1986), reprinted in 1986 U.S.C.C.A.N 6344. While petitioner need not show that the vaccine was the sole or even predominant cause of the injury, petitioner bears the burden of establishing "that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Shyface, 165 F.3d at 1352-53. Petitioners do not meet their affirmative obligation to show actual causation by simply demonstrating an injury which bears similarity to a Table injury or to the Table time periods. Grant, 956 F.2d at 1148. See also H.R. Rep. No. 99-908, Pt. 1, at 15 (1986), reprinted in 1986 U.S.C.C.A.N 6344. Nor do petitioners satisfy this burden by merely showing a proximate temporal association between the vaccination and the injury. Grant, 956 F.2d at 1148 (quoting Hasler v. United States, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984) (stating "inoculation is not the cause of every event that occurs within the ten day period [following it]. . . . Without more, this proximate temporal relationship will not support a finding of causation")); Hodges, 9 F.3d at 960. Finally, a petitioner does not demonstrate actual causation by solely eliminating other potential causes of the injury. Grant, 956 F.2d at 1149-50; Hodges, 9 F.3d at 960.

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[31]The general acceptance of a theory within the scientific community can have a bearing on the question of assessing reliability while a theory that has attracted only minimal support may be viewed with skepticism. Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 594 (1993). Although the Federal Rules of Evidence do not apply in Program proceedings, the United States Court of Federal Claims has held that "Daubert is useful in providing a framework for evaluating the reliability of scientific evidence." Terran v. Secretary of HHS, 41 Fed. Cl. 330, 336 (1998), aff'd, 195 F.3d 1302, 1316 (Fed. Cir. 1999). In Daubert, the Supreme Court noted that scientific knowledge "connotes more than subjective belief or unsupported speculation." Daubert, 509 U.S. at 590. Rather, some application of the scientific method must have been employed to validate the expert's opinion. Id. Factors relevant to that determination may include, but are not limited to:

> whether the theory or technique employed by the expert is generally accepted in the scientific community; whether it's been subjected to peer review and publication; whether it can be and has been tested; and whether the known potential rate of error is acceptable.

Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1316 (9th Cir. 1995) (Kozinski, J.), on remand from 509 U.S. 579 (1993); see also Daubert, 509 U.S. at 592-94.

With these long-standing principles in mind, the undersigned established a five-prong test for demonstrating causation-in-fact by a preponderance of the evidence in the absence of epidemiological evidence. See Stevens v. Secretary of HHS, No. 99-594V, 2001 WL 387418 (Fed. Cl. Spec. Mstr. Mar. 30, 2001). The standard requires that petitioner provide proof of (1) medical plausibility, (2) confirmation of medical plausibility from the medical community and literature, (3) an injury recognized by the medical plausibility evidence and literature, (4) a medically acceptable temporal relationship between the vaccination and the onset of the alleged injury, and (5) the reasonable elimination of other causes. Stevens, 2001 WL 387418, at *23-*26; see also Watson v. Secretary of HHS, No. 96-639V, 2001 WL 1682537, at *19 (Fed. Cl. Spec. Mstr. Dec. 18, 2001). The court addresses petitioner's Table and off-Table claims below.

V. DISCUSSION

Petitioner's Table encephalopathy claim

The Vaccine Injury Table promulgated by the Secretary's February 20, 1997 Final Rule governs this claim. 62 Fed. Reg. 7685 (Feb. 20, 1997) (codified at 42 C.F.R. §100.3 (1997)). See also 60 Fed. Reg. 7678, 7694-95 (Feb. 8, 1995) (codified at 42 C.F.R. §100.3 (1995)) (implementing the bulk of the substantive changes to the encephalopathy definition which applies in this case). Petitioner must demonstrate first that an acute encephalopathy occurred "not less than 5 days and not more than 15 days" after the vaccine's administration and, second, that a chronic encephalopathy persisted "for more than 6 months beyond the date of vaccination." §100.3(a); §100.3(b)(2); see also §100.3(b)(2)(ii). "An acute encephalopathy is one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred)." §100.3(b)(2)(i). In this case, because Hunter presented with a seizure event at 13 months of age, petitioner must show his acute encephalopathy involved a "significantly decreased level of consciousness [which] persist[ed] beyond 24 hours and cannot be attributed to a postictal state (seizure) or medication." §100.3(b)(2)(i)(A). According to the applicable definition,

> [a] "significantly decreased level of consciousness" is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater (see paragraphs (b)(2)(i)(A) and (b)(2)(i)(B) of this section for applicable timeframes):
>
> > (*1*) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);
> > (*2*) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or
> > (*3*) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

§100.3(b)(2)(i)(D). In addition, "[i]ncreased intracranial pressure may be a clinical feature of acute encephalopathy in any age group." §100.3(b)(2)(i)(C). Evaluating petitioner's claim in light of these requirements, the court finds that neither Dr. Lewis's testimony nor the medical records support that

Hunter suffered a Table encephalopathy following his May 1, 1996 MMR.

First, Dr. Lewis does not base his opinion that Hunter suffered a Table encephalopathy on the definition set forth above. See, e.g., Tr. I at 10-11 (Dr. Lewis admitting he cannot recall which definition he relied on when assessing Hunter's medical records).[32] Instead, he focuses on his disagreement with §100.3(b)(2)'s requirements. He notes the difficulty in proving 24 hours of altered level of consciousness when the standard treatment for seizures involves some form of medication, which cannot be a factor under the statute. Id. at 10. He then offers that "[n]ormally, neurology uses encephalopathy quite loosely. They say, basically, it's something wrong with the brain. . . . It may be transient or it may produce injur[y] that's permanent. But encephalopathy in [his] book just means a problem in the brain. It's a very loose term." Id. at 11. Based on this loose definition, Dr. Lewis believes Hunter clearly "had something wrong with his brain" and "when you have a seizure and a fever, you have, by . . . definition, an encephalopathy." Id. He adds that Hunter's 20 minute "complicated febrile convulsion" is enough for him to call the seizure event an encephalopathy of some form. Id. Unfortunately for petitioner, Dr. Lewis's clinical or neurological definitions for encephalopathy do not comport with the Act's, and the court cannot find in petitioner's favor based on his opinion. See Watt v. Secretary of HHS, No. 99-25V, 2001 WL 166636, at *7-*8 (Fed. Cl. Spec. Mstr. Oct. 26, 2000) (reissued for publication Jan. 26, 2001) (stating that the court's responsibility is to interpret and apply the "Qualifications and aids to interpretation" as Congress wrote them, not "as others believe they should be written").

Second, petitioner's claim is unsupported by the medical records, as Dr. MacDonald explained cogently. Quite simply, the records do not corroborate that Hunter suffered a 24-hour seizure as his parents aver, nor do they support he suffered a significantly decreased level of consciousness lasting at least 24 hours, irrespective of the Valium he received as treatment for his seizure. While Hunter's treaters described him as unresponsive, apneic, and "comatose" immediately following his seizure, they did not diagnose an encephalopathy. The records show further he had "good eye contact" within one hour after the convulsion. Within hours after that, he was alert enough to extubate himself upon arrival to the Naval Medical Center. By early morning, Hunter remained groggy or "drowsy from Valium," "but more awake and alert." He recognized his parents. By 1:00 p.m. on the day following his seizure, Hunter was "awake and alert" and smiled and laughed with his parents. These descriptions do not evidence a child with a persistent and significantly decreased level of consciousness lasting 24 hours or more, as required by §100.3(b)(2)(i)(A). Nor do the records document any increased intracranial pressure, another indicator of an encephalopathic injury. Moreover, Hunter's clinical features of pre-seizure fussiness, seizure and lethargy or sleepiness following his convulsion, alone or in combination, are all insufficient evidence of an acute encephalopathy or "a significant change in either [his] mental status or [his] level of consciousness." See §100.3(b)(2)(i)(E). Finally, Hunter repeatedly received normal neurological and developmental evaluations following his first seizure, compelling evidence he sustained no chronic encephalopathy in the six months following his May 9th seizure, even had he suffered an acute encephalopathic injury. See §100.3(b)(2)(ii) ("Individuals who return to a normal

[32]Certainly, Hunter suffered his first seizure within the 5-15 day Table time period.

neurologic state after the acute encephalopathy shall not be presumed to have suffered residual neurologic damage from that event; any subsequent chronic encephalopathy shall not be presumed to be a sequela of the acute encephalopathy."). Absent supportive medical records or credible expert testimony, petitioner's Table encephalopathy claim fails. See §13(a)(1).

Petitioner's causation-in-fact claim

Petitioner submitted no epidemiologic study relevant to her claim that the MMR vaccine caused Hunter's injuries and the government presented no epidemiologic evidence to the contrary. No epidemiologic studies apparently exist on the relation. Therefore, the court will apply Stevens's five-prong circumstantial evidence test.[33] Again, petitioner must prove (1) medical plausibility, (2) confirmation of medical plausibility from the medical community and literature, (3) an injury recognized by the medical plausibility evidence and literature, (4) a medically acceptable temporal relationship between the vaccination and the onset of the alleged injury, and (5) the reasonable elimination of other causes. Stevens, 2001 WL 387418, at *23-*26; see also Watson, 2001 WL 1682537, at *19.

In analyzing this case pursuant to Stevens, petitioner offers only Dr. Lewis's testimony that it is medically plausible for the vaccine to cause Hunter's partial complex seizure disorder or hippocampal sclerosis and that his own work shows seizures can cause hippocampal injury. However, he provides no support from the medical community or the literature for these opinions.[34] He further admits science is at odds over which comes first, the seizures or the hippocampal injury.

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[33]The parties did not accept the court's invitation to file closing briefs and address the Stevens test. See Orders, filed April 19, 2001 and December 6, 2001.

[34]Petitioner also provides no literature that the MMR vaccine can cause a febrile seizure. The IOM concluded "[t]he evidence is inadequate to accept or reject a causal relation between measles vaccine and residual seizure disorder" and "[t]here is no evidence bearing on a causal relation between mumps vaccine and residual seizure disorder." R. Ex. A at 145 (Kathleen R. Stratton et al., Institute of Medicine, Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality 142-45 (1994)). While the Institute noted evidence exists for acute seizures following the measles vaccine and "[t]herefore, it is biologically plausible that there is a connection between immunization and RSD," the authors also stated "it would be essential to rule out the possibility that the acute cases described in the literature are not febrile seizures, which are common in children and which would not be expected to lead to an RSD." Id. In this case, Hunter suffered a febrile seizure on day eight. In addition, none of the cases reviewed by the IOM show a causal relation between a febrile seizure and permanent neurologic sequelae such as that which developed in this case. Id. at 142-45. See also R. Ex. E at 1, 3 (Heikki Peltola, et al., Mumps and Rubella Eliminated From Finland, 284 JAMA 2643, 2645 (2000) (stating that "[n]o death or permanent sequelae have been encountered" in the MMR study detailed therein).

There is also no evidence Hunter sustained his hippocampal sclerosis in a medically acceptable time period following the vaccination. Dr. Lewis makes several damaging concessions in this regard. He concedes he "can't prove from the medical records that [Hunter's] brain was permanently injured" immediately following the first seizure. Tr. I at 12, 34; see also Tr. I at 13, 41. He explains physicians can only prove hippocampal sclerosis by performing an MRI within 72 hours following the seizure to see if the patient suffers first a swollen hippocampus and then shrinkage of the brain component. Id. at 12, 34, 37. This was not done in Hunter's case.[35] He also agrees science is not sure exactly *when* after the seizure activity the hippocampal injury occurs, immediately or later, or how the injury will manifest clinically. Id. at 46. From this Dr. Lewis concedes that Hunter's seizure activity in October 1996, *five months after the first seizure*, could have caused his hippocampal injury. Id. at 46-47. As Dr. Lewis noted, he simply cannot prove his theory – that the MMR caused Hunter's fever, the fever caused the seizure, and then the seizure caused the hippocampal sclerosis resulting in the subsequent seizure disorder and learning and behavioral problems. Id. at 12, 13, 41.

In addition, there is strong evidence from the MRIs that Hunter suffered his hippocampal injury sometime between his normal November 1996 and abnormal June 1997 scans. Such evidence more probably than not places Hunter's brain damage outside of any medically acceptable time frame for causation. Certainly, petitioner has produced no literature that hippocampal sclerosis developing more than six months after the vaccination can more probably than not be causally related back to the MMR. The court agrees with Dr. MacDonald that the change in the MRI findings between November and June "support the conclusion that the child's chronic neurological problems developed later in the clinical course and are not directly related to the MMR given on May 1, 1996." R. Ex. C at 1. The scans and the testimony are further supported by the medical records in this case, which consistently document normal neurological and developmental exams, head circumference results, and CT readings in the nine months between Hunter's first seizure and Dr. Lewis's exam in February 1997. Furthermore, Hunter's parents and his treating physicians consistently related any behavioral concerns to Hunter's medication and adjusted his dosages accordingly. Without more, the court cannot conclude Hunter suffered a compensable injury within a medically acceptable time frame following vaccination.

Moreover, petitioner has not convincingly demonstrated the elimination of reasonable alternative causes through differential diagnosis.[36] Dr. Lewis admits the possibility that an infection

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[35]Dr. Lewis opines that while CT scans are not performed to view the hippocampus and he did not review Hunter's, the hippocampal injury would show up there as well. Tr. I at 7-8. But, the records evidence Hunter's normal CT immediately following his first seizure.

[36]This is not the "factor unrelated" burden, but is part of the differential diagnosis process that doctors engage in in reaching the opinion that more probably than not the vaccine caused the injury. Differential diagnosis is consistently a key component of experts' opinions and thus is an essential element of Stevens. See Watson, 2001 WL 1682537, at *19-*28.

caused Hunter's prolonged fever and bronchi findings. See, e.g., Tr. I at 26-28. He agrees also an *infection* may cause a hippocampal injury and manifest later as temporal epilepsy. Id. at 47-48. He agrees further that Hunter was diagnosed with and treated for an ear infection (otitis media) which could be a "real good cause" of his fever and subsequent febrile convulsion. Id. at 23, 24-25, 33. While maintaining consistently that Hunter did not have a mild infection on May 9, 1996, he concurs viral illness symptoms can include diarrhea, cough, and high fever. Id. at 21-22, 29-30. He further accepts that if Hunter had these symptoms and slight otitis media, fussiness, and an elevated WBC count, these "could be" an indication he was fighting a viral infection. Id. at 27. According to the records, Hunter experienced these exact symptoms following his vaccination and on the day of his febrile seizure. P. Ex. L at 11, 12-13, 18, 20. Over the course of his hospitalization, Hunter's fever continued for nearly 48 hours and he experienced loose stools and minimal erythema around his left TM. His treating physicians repeatedly questioned whether Hunter had left otitis media, gastroenteritis, or viral pneumonia. See, e.g., id. at 12-13; P. Ex. M at 5, 6, 14, 15, 20, 39, 44, 45. He was ultimately discharged with a final diagnosis of febrile seizure, post-valium overdose, and a left ear infection. His course of treatment during hospitalization and following his discharge included medication with Amoxil for his previously diagnosed otitis media. Hence, the medical records and Dr. MacDonald's credible testimony (see, e.g., Tr. I at 52-56; Tr. II at 10, 11, 12-13, 16-17) demonstrates more probably than not that Hunter experienced a viral illness following his vaccination, as indicated by his left otitis media diagnosis and treatment. Thus, the differential diagnosis does not lead to the probable role of the vaccine as the causative agent. The lack of proof positive of the vaccine's role coupled with this major hole in the Stevens's deductive reasoning – the inconclusive result of the differential diagnosis – leaves petitioner's case as an exercise in educated speculation. Speculation cannot support a probability finding. See Snowbank Enter. v. United States, 6 Cl. Ct. 476, 486 (1984); Silva v. Secretary of HHS, No. 90-1098V, 1992 WL 700265, at *7 (Cl. Ct. Spec. Mstr. May 22, 1992). Based on the above, petitioner's actual causation claim fails.[37]

[37]Dr. MacDonald offered the more credible testimony in this case. His responses were cogent, persuasive, and relevant. Dr. Lewis, on the other hand, consistently demonstrated unfamiliarity with the information contained in the medical records and failed to address the real causation issues in this case. See, e.g., Tr. I at 5, 20, 22, 24-25, 26, 34, 35, 42. He also expressed many of his opinions in terms of a "possible" versus "probable" connection to the vaccine, which is insufficient to demonstrate actual causation. See Haynes v. Secretary of HHS, No. 95-716V, 1999 WL 199048, at *17, n. 51 (Fed. Cl. Spec. Mstr. Mar. 15, 1999) (citing Lacour v. Secretary of HHS, No. 90-316V, 1991 WL 66579, at *5 (Cl. Ct. Spec. Mstr. Apr. 15, 1991)). While Dr. Lewis's efforts on behalf of this injured child were laudable, they were far from convincing.

VI. CONCLUSION

Based on the foregoing, the undersigned finds, after considering the entire record in this case, that petitioner is not entitled to compensation under the Vaccine Act.[38] In the absence of a motion for review filed pursuant to RCFC Appendix J, the Clerk of the Court is directed to enter judgment in accordance herewith.

IT IS SO ORDERED.

Gary J. Golkiewicz
Chief Special Master

[38]To be sure, the court makes no suggestion that Hunter's parents pursued this claim in bad faith. Their constant care and attention to his needs, quite apparent from the medical records, is admirable. They appear to be devoted parents with a firmly held belief that the MMR vaccine injured their son. Congress, however, designed the Program to compensate only those individuals who can demonstrate a causal or temporal link between their injuries and a listed vaccine by a preponderance of the evidence. In this case, the evidence simply does not demonstrate such a link.